

03-13-06

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# TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT (Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
323-100 US D

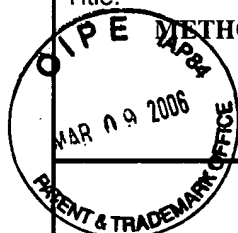
In Re Application Of:

SUZANNE ZEBEDEE, ET. AL.

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/677,956	10/01/2003	ZACHARIAH LUCAS	NONE	1648	9260

Title:

METHOD AND SYSTEMS FOR PRODUCING RECOMBINANT VIRAL ANTIGENS



Address to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## 37 CFR 1.97(b)

1. ☐ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

## 37 CFR 1.97(c)

2. ☒ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

- ☐ the statement specified in 37 CFR 1.97(e);

OR

- ☒ the fee set forth in 37 CFR 1.17(p).

03/15/2006 AKELECH1 00000046 134892 10677956

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**METHOD AND SYSTEMS FOR PRODUCING RECOMBINANT VIRAL ANTIGENS**

**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. 13-4892 as described below.
- ☒ Charge the amount of \$180.00
- ☒ Credit any overpayment.
- ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

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Joseph E. Mueth  
Signature

Dated: **March 9, 2006**

JOSEPH E. MUETH, ESQ.  
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**CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)**

Applicant(s): Zebedee, Suzanne, et al.

Docket No.

323-100US D

Application No.

10/677,956

Filing Date

10/01/2003

Examiner

Zachariah Lucas

Customer No.

None

Group Art Unit

1648

METHOD AND SYSTEMS FOR PRODUCING RECOMBINANT VIRAL ANTIGENS

I hereby certify that the following correspondence:

Letter Regarding Okamoto, et al. Paper; Transmittal of Information Disclosure Statement; Information Disclosure Statement by Applicant; Certificate of Mailing by "Express Mail"

*(Identify type of correspondence)*

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

March 9, 2006*(Date)*SALLY SHORE*(Typed or Printed Name of Person Mailing Correspondence)*  
*(Signature of Person Mailing Correspondence)*EV 738852903 US*("Express Mail" Mailing Label Number)***Note: Each paper must have its own certificate of mailing.**

10/677,956



Attorney Docket No. 323-100US-D

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	Group Art Unit: 1648
	)	
ZEBEDEE et al.	)	Examining Attorney:
	)	Zachariah Lucas
Serial No.: 10/677,956	)	
	)	Date: March 9, 2006
Filed: October 1, 2003	)	Pasadena, California
	)	
For: METHODS AND SYSTEMS FOR	)	
PRODUCING RECOMBINANT	)	
VIRAL ANTIGENS	)	

**LETTER REGARDING OKAMOTO, ET AL. PAPER,**

**JAPAN J. EXP. MED., VOL. 60, NO. 4, PP. 223-233 (1990)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Attached please find a copy of Okamoto, et al., Japan J. Exp. Med., Vol. 60, No. 4, pp. 223-233 (1990). This paper was previously cited in the Information Disclosure Statement filed herein on November 24, 2003. The front cover of the journal containing the Okamoto, et al. paper carries the month of August, 1990, as the date of publication.

The Okamoto, et al. paper discloses some findings on HCV seroconversion specimens, using an ELISA assay and synthetic peptides, none of which are identical to the recombinant constructs disclosed in ultimate parent Patent Application Serial No. 573,643, filed August 27, 1990, attached to the Declaration of Joseph E. Mueth, filed February 13, 2006. However, the paper supports applicants' discovery as defined in claims 102 to 111 that the capsid is an effective antigen to detect the appearance, in the serum of individuals infected with HCV (NANBV), of antibodies directed against this organism.

Applicants have conducted an investigation and determined that the Okamoto, et al. is not "prior art" because it was not available to the public prior to applicants' effective filing date of August 27, 1990.

Applicant has now contacted what is believed to be a representative cross-section of libraries in Japan, Europe and in this country. There is no evidence that any library received the Okamoto paper prior to August 27, 1990. To the contrary, the Okamoto paper did not become available to the public until after the priority date of August 27, 1990 claimed in the present application.

The following evidence is provided herewith and shows the results of the library search:

a) Tokyo University Medical Library

The Certificate from the Library regarding Japanese Journal of Experimental Medicine, Vol. 60, No. 4, pp. 223-233 gives the Library accepted date as November 1, 1990.

b) University Library, University of California at San Francisco

The received date is given as December 27, 1990.

c) Japanese National Diet Library

The Certificate from the Diet Library is attached and gives an accession date of October 31, 1990.

d) General Library of the University of Tokyo

The cover sheet with date stamp of the receiving section states the accession date October 31, 1990.

e) United States National Library of Medicine (NIH)

This is the United States reference library for documents to be used in legal proceedings. The "date stamp page" (cover page) clearly documents that this library had recorded the issue "Japanese Journal of Experimental Medicine vol. 60, no. 4" as received on December 23, 1991.

f) United States University of Missouri-Columbia

The date stamp is found on the right hand side on the cover sheet and the accession date recorded is January 4, 1991.

g) United States University of Wisconsin-Madison

The date stamp is found on the right hand side lower corner and it is evident that the journal in question was available on January 8, 1991.

h) United States University of Michigan (Taubman, Medical Library)

The corresponding receiving date is found on the left hand corner of the cover page and is evident to be January 4, 1991.

i) British Library, London, United Kingdom

As is evident on the right hand side of the cover sheet, the accession sheet in the British library was February 6, 1991.

j) Certificate from the Librarian of the Karolinska Institute of Stockholm, Sweden

In this certificate, Eva Bregoli certified that the "Japanese Journal of Experimental Medicine, vol. 60, no. 4" was received in Stockholm, Sweden on May 13, 1991.

Accordingly, Applicant has provided a total 10 documents which clearly prove that the earliest public accession date of Okamoto, et al., "Japanese J. of Exp. Med., vol. 60, no. 4" was October 31, 1990.

Accordingly, the Okamoto, et al. paper is not be considered as "prior art" in the sense of 35 U.S.C. 102.

Date: March 9, 2006

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. E. Mueth", is written over the printed name.

Joseph E. Mueth  
Registration No. 20,532

225 South Lake Avenue, 8th Floor  
Pasadena, California 91101  
Telephone: (626) 584-0396  
Facsimile: (626) 584-6862



**Complete if Known**

*(Use as many sheets as necessary)*

Sheet	1	of	4
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[illegible][illegible]

Date	
Considered	

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			<b>Complete if Known</b>	
	Application Number	10/677,956		
	Filing Date	10/01/2003		
	First Named Inventor	Suzanne Zebedee		
	Art Unit	1648		
	Examiner Name	Zachariah Lucas		
	Attorney Docket Number	323-100US D		
Sheet	2	of	4	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		HOUGHTON, ET AL., Int. K. Prot. Res., 16:311-320 (1980)	
		CHOO, ET AL., Science, 244:359-362 (1989)	
		ALTER, ET. AL., NEJM, 321:1538-39 (1989)	
		KUO, ET AL., Science, 244:362-364 (1989)	
		MEYERS, ET AL., Virol., 171:555-567 (1989)	
		KATO, ET AL., PNAS, 87:9524-9528 (1990)	
		GRAY, ET AL., Lancet, 335:609-610 (1990)	
		MCFARLANE, ET AL., Lancet, 335:754-757 (1990)	
		WEINER, ET AL., Lancet, 335:1-3 (1990)	
		MILLER, ET AL., PNAS, 87:2057-2061 (1990)	
		TAKEUCHI, ET AL., Nucl. Acids Res., 18:4626 (1990)	

Examiner Signature		Date Considered	
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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				Filing Date	10/01/2003
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				Art Unit	1648
				Examiner Name	Zachariah Lucas
				Attorney Docket Number	323-100US D

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		PRINCE, ET AL., "Long-Incubation of Post-Transfusion Hepatitis Without Serological Evidence of Exposure to Hepatitis-B Virus", The Lancet, 2:241 (1974)	
		PRINCE, ET AL., "Posttransfusion Viral Hepatitis caused by an Agent or Agents Other than Hepatitis B Virus or Hepatitis A Virus. Impact on Efficiency of Present Screening Methods", Transmissible Disease & Blood Transfusion, Tibor et al. eds., Grune & Stratton, Inc., pp. 129-140 (1975)	
		PRINCE, ET AL., "Non-A/Non-B Hepatitis: Identification of a Virus-specific Antigen and Antibody. A Preliminary Report", Viral Hepatitis, Vyas et al. eds., Franklin Institute Press, Philadelphia, PA, pp. 633-640.	
		PRINCE, ET AL., "Non-A, Non-B Hepatitis: Reproduction Of Disease In Chimpanzees And Identification Of Virus Specific Antigen and Antibody", Transplantation and Clinical Immunology, Vol. X, Touraine et al. eds., Excerpta Medica, Amsterdam, pp. 8-17 (1979)	
		PRINCE, A.M., "Nature of Non-A, Non-B Hepatitis Viruses", The Lancet, pp. 1181-2, May, 22, 1982	
		PRINCE, ET AL., "Use of Liver Cell Cultures in Studies on the Replication of Hepadna and Non-A, Non-B Viruses", Viral Hepatitis and Liver Disease, Grune & Stratton, pp. 459-464 (1984)	
		BROTMAN, ET AL., "Non-A, Non-B Hepatitis: Is There More Than a Single Blood-Borne Strain?", J. Infect. Diseases, Vol. 151, No. 4, pp. 618-625 (1985)	
		BRINTON, ET AL., "Sequence and Secondary Structure Analysis of the 5'-Terminal Region of Flavivirus Genome RNA", Virol., 162:290-299 (1988)	
		COLLETT, ET AL., "Molecular Cloning and Nucleotide Sequence of the Pestivirus Bovine Viral Diarrhea Virus", Virol., 165:191-199 (1988)	
		HAHN, ET AL., "Nucleotide Sequence of Dengue 2 RNA and Comparision of the Encoded Proteins with Those of Other Flaviviruses", Virol., 162:167-180 (1988)	
		TAKEUCHI, ET AL., "Hepatitis C viral cDNA clones isolated from a healthy carrier donor implicated in post-transfusion non-A, non-B hepatitis", Gene, 91:287-291 (1990)	

Examiner Signature		Date Considered	
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<i>Filing Date</i>	10/01/2003
		<i>First Named Inventor</i>	Suzanne Zebedee
		<i>Art Unit</i>	1648
		<i>Examiner Name</i>	Zachariah Lucas
		<i>Attorney Docket Number</i>	323-100US D
Sheet	4	of	4

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		SUTCLIFFE, ET AL., "Antibodies That React with Predetermined Sites on Proteins", Science, Vol. 219. No. 4585, pp. 600-666 (1983)	
		GERBER, ET AL., "Biology of Disease: Molecular and Cellular Pathology of Hepatitis B", Laboratory Investigation, Vol. 52, No. 6, pp. 572-590 (1985)	
		SMITH, ET AL., "Single-step purification of polypeptides expressed in Escherichia coli as fusions with glutathione S-transferase", Gene, 67:31-40 (1988)	

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